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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,622	07/14/2000	Kristoffer Hellstrand	MAXIM.078A	6563

20995 7590 07/26/2002

KNOBBE MARTENS OLSON & BEAR LLP
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH, CA 92660

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,622

Applicant(s)

Hellstrand et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 25, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 2-7 and 14-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. In view of Applicant's amendment and response, filed 4/25/02, the previous rejections under the second paragraph of 35 U.S.C. 112 have been withdrawn.

2. Claims 1 and 8-13 are being acted upon.

3. The amendment filed 4/25/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amending at pages 7 and 12 of "diphenylionodonium" to "diphenylene idonium." Said change comprises the introduction of new matter into the specification and is therefore impermissible.

Appropriate correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 8-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence that the claimed method would function for activating cytotoxic lymphocytes or for protecting cytotoxic lymphocytes after administering DPI to a patient, for the reasons of record as set forth in Paper No. 8, mailed 11/20/01.

Applicant's arguments, filed 4/25/02, have been fully considered but they are not persuasive. Applicant argues that, Examples 2 and 3 adequately describe the claimed invention and that "Figure 1 unequivocally demonstrates that DPI significantly increased the CD69 expression on T-cells (left panel) over IL-2 alone in the presence of MO, proving that DPI activates MO-inhibited T-cells stimulated by IL-2." It is the Examiner's position that the figure is insufficient to support the breadth

of the claims. It is noted that in the Brief Description of the Drawings that the figure discloses only "Protection of CD3e+ T-cells against oxidative inhibition by DPI." There is no mention of activation. Further, it is disclosed that "A mixture of MO and lymphocytes was treated with culture medium (control, open circles) or IL-2 (100 U/ml; filled circles) for 16 hrs." Thus, there is no demonstration of the effect of DPI treatment absent IL-2 (a well-known cytotoxic cell activator). Applicant fails to argue how Example 3, an assay of FasL/Fas interactions, supports the invention of the instant claims.

Applicant asserts, that in regards to Claim 13 drawn to the inhibition of hydrogen peroxide, "the present application provides sufficient teachings with which to assay hydrogen peroxide production inhibition." While the assertion may be true, the claim is not drawn to a method of assaying hydrogen peroxide production, but rather a method of inhibiting said production, which is not enabled by the instant specification for the reasons of record.

6. Claims 1 and 8-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of a "cytotoxic lymphocyte" other than an NK or cytotoxic T cell, for the reasons of record as set forth in Paper No. 8, mailed 11/20/01.

Applicant's arguments, filed 4/25/02, have been fully considered but they are not persuasive. Applicant argues that, "it is well known in the art that the only two "cytotoxic lymphocyte" types are the NK and the cytotoxic T cells." While this may be true, the specification at page 10 specifically defines the term to include other cell types. "Cytotoxic lymphocytes also encompasses non-cytotoxic cells such as T-helper cells that assist in the activation of a lymphocyte with cytotoxic capabilities." As such, it remains the Examiner's position that the specification fails to disclose a representative number of species to describe the claimed genus.

7. The following are new grounds of rejection necessitated by Applicant's amendment.

8. Claims 1 and 8-13 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) in Claim 1, diphenylene iodonium,
- B) in Claims 9 and 10, a compound that inhibits the production and release of intercellular reactive oxygen metabolites.

Applicant asserts that "these amendments do not change the scope of the claims at issue but rather merely clarify the subject matter recited therein." However, Applicant fails to assert that no new matter has been introduced into the claims and no support for the new limitations has been found in the specification.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

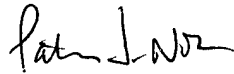
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
July 25, 2002


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600